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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,476	11/25/2003	Edward J. Gough	A-70576/ENB	7642
32940	7590	07/17/2006	EXAMINER	
DORSEY & WHITNEY LLP 555 CALIFORNIA STREET, SUITE 1000 SUITE 1000 SAN FRANCISCO, CA 94104			BOUCHELLE, LAURA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,476	<b>Applicant(s)</b> GOUGH ET AL.	
	<b>Examiner</b> Laura A. Bouchelle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 16-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/9/06, 5/24/04</u> <b>5/10/04</b> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 16-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/22/2006.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverman et al (US 6251064). Silverman discloses an injection apparatus comprising a first tubular member 42, a second tubular member 43 slidably received in first member, the distal end of the second tubular member comprises a needle, and a reservoir for a biocompatible composition and a biocompatible solvent (Col. 3, lines 35-40). The biocompatible composition can comprise a biocompatible prepolymer (Col. 6, lines 45-50).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita (US 6228059). Silverman discloses that an optical element is disposed in the passageway. Claim 1 differs from Silverman in calling for a locking mechanism to lock the second tubular member with respect to the first tubular member. Astarita teaches an endoscopic instrument having a locking mechanism to lock the inner tubular member relative to the outer tubular member so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman to include a locking mechanism as taught by Astarita so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita as applied to claim 1 above, and further in view of Silverman et al (US 6251063) [Hereinafter Silverman II]. Claim 2 differs from the teachings of Silverman in view of Astarita in calling for the needle to be made of metal and the tubular portion to

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be made of plastic. Silverman II teaches an injection device having a metal needle and a plastic tubular member because such materials provide the required structural characteristics and are easy to manufacture. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita to have a metal needle and a plastic tubular member as taught by Silverman II because such materials provide the required structural characteristics and are easy to manufacture.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita as applied to claim 3 above, and further in view of Kikawada (US 5637075). Claim 4 differs from Silverman in calling for a first and second optical element. Claim 5 differs in calling for the optical element to have an inclined end surface. Kikawada teaches a device for observing the inside of a body cavity having a first optical element for supplying light and a second optical element for receiving reflected light that allows for the physician to visualize the body cavity to facilitate proper placement of the medical device (Col. 1, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita to have a first and second optical element as taught by Kikawada the physician can visualize the body cavity to facilitate proper placement of the medical device.

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8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman in view of Astarita as applied to claim 1 above, and further in view of Morrison (US 4609370). Claim 6 differs from the teachings above in calling for the needle to have a distal face inclined at an angle greater than 25 degrees. Claim 7 calls for the angle to be approximately 30 degrees. Morrison teaches a needle assembly having a needle with an angle of approximately thirty degrees to allow for easy insertion into the tissue (Col. 5, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita to have a needle with an incline of approximately thirty degrees as taught by Morrison to allow for easy insertion into the tissue.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

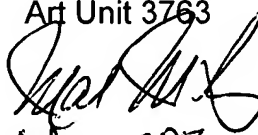
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

Laura A Bouchelle  
Examiner  
Art Unit 3763



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